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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 22-V-2007
C(2007)2262

NOT FOR PUBLICATION

COMMISSION DECISION

of 22-V-2007

**amending the marketing authorisation for "Thelin - Sitaxentan sodium", a
medicinal product for human use, granted by Decision C(2006)3721**

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

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amending the marketing authorisation for "Thelin - Sitaxentan sodium", a medicinal product for human use, granted by Decision C(2006)3721

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency¹,

Having regard to Commission Regulation (EC) No 1085/2003 of 3 June 2003 concerning the examination of variations to the terms of a marketing authorisation for medicinal products for human use and veterinary medicinal products falling within the scope of Council Regulation (EEC) No 2309/93², and in particular the first subparagraph of Article 6(10) thereof,

Having regard to the application(s) submitted by Encysive (UK) Limited on 15 October 2006 under Article 6(1) of Commission Regulation (EC) No 1085/2003,

Having regard to Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use³, and in particular Article 61(3) thereof,

Having regard to the opinion(s) of the European Medicines Agency, formulated by the Committee for Medicinal Products for Human Use on 22 February 2007,

Whereas:

- (1) An examination of the major variation(s) type II to the terms of the marketing authorisation for the medicinal product "Thelin - Sitaxentan sodium", which is entered in the Community Register of Medicinal Products under number(s) EU/1/06/353/001-005 and the placing on the market of which was authorised by

¹ OJ L 136, 30.4.2004, p. 1, Regulation as amended by Regulation (EC) No 1901/2006 (OJ L 378, 27.12.2006, p.1).

² OJ L 159, 27.6.2003, p. 24.

³ OJ L 311, 28.11.2001, p. 67, Directive as last amended by Regulation (EC) No 1901/2006 (OJ L 378, 27.12.2006, p.1).

Decision C(2006)3721 of 10 August 2006, has shown that the product remains in compliance with the requirements set out in Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use⁴.

- (2) The marketing authorisation should be subject to compliance with revised conditions, set out in Annex II to this decision. The implementation of certain of these conditions with regard to the safe and effective use of the medicinal product is to be ensured by the Member States, in accordance with Article 127a of Directive 2001/83/EC. To this effect, Commission Decision C(2007)2261 of 22-V-2007 is simultaneously being addressed to the Member States.
- (3) It is therefore appropriate to accept the application(s) in respect of (a) major variation(s) to the terms of the marketing authorisation and to amend Decision C(2006)3721 accordingly.
- (4) Encysive (UK) Limited submitted, under Article 61(3) of Directive 2001/83/EC, a notification(s) for changes to an aspect of the labelling or the package leaflet, which has (have) not yet been included in Decision C(2006)3721 of 10 August 2006.
- (5) The marketing authorisation should be updated, and Decision C(2006)3721 amended accordingly.

HAS ADOPTED THIS DECISION:

Article 1

Decision C(2006)3721 is amended as follows:

1) The following list of notifications for changes to an aspect of the labelling or the package leaflet is added to the updated marketing authorisation;

Application number	Annex (EU numbers affected)
EMEA/H/C/679/N/02	IIIAB (EU/1/06/353/001-005)

2) Annex I is replaced by the text set out in Annex I to this Decision;

3) Annex II is replaced by the text set out in Annex II to this Decision;

4) Annex III is replaced by the text set out in Annex III to this Decision.

⁴ OJ L 311, 28.11.2001, p. 67, Directive as last amended by Regulation (EC) No 1901/2006 (OJ L 378, 27.12.2006, p.1).

Article 2

This Decision is addressed to Encysive (UK) Limited, Alder Castle House, 10 Noble Street, London EC2V 7QJ, United Kingdom.

Done at Brussels, 22-V-2007

For the Commission
Heinz ZOUREK
Director-General